



vaccinations caused his fibromyalgia. Fibromyalgia is defined as “a common syndrome of chronic widespread soft-tissue pain accompanied by weakness, fatigue, and sleep disturbances.” Stedman’s Medical Dictionary, 28th Ed., 2006, at 725. As fibromyalgia (“FM”) is not an injury listed on the Vaccine Injury Table, there is no presumption of causation. Therefore, petitioner is required to prove by a preponderance of the evidence that the vaccine in-fact caused his FM.

The case proceeded in a traditional manner, progressing from the filing of records, the respondent’s Rule 4(c) Report, and competing expert reports, to the taking of factual and expert testimony. The case transferred to the undersigned after the first Hearing in February 2008, wherein testimony was heard from petitioner and the parties’ experts. After the transfer, petitioner chose to revisit only the factual testimony of petitioner, leaving the expert testimony from the first Hearing to stand. Factual testimony was taken from petitioner in December 2008, after which the parties opted to not file post-hearing briefs.

This case involved notable effort invested by both parties. However, upon reviewing the case in its entirety, the undersigned finds that petitioner has not demonstrated by a preponderance of the evidence that his receipt of the Hep B vaccines caused his FM. Although petitioner’s expert is a well-credentialed expert capable of testifying in this matter, his convoluted and questionable approach to proving this case fails under even superficial scrutiny. Furthermore, when one takes into consideration the report and testimony of respondent’s expert, who has more experience in treating patients with FM, petitioner’s evidence is even more unpersuasive. Ultimately, petitioner fails to meet his burden, most apparently that of the appropriate temporal relationship between the vaccinations and the alleged injury.

## I. FACTUAL HISTORY

Petitioner was born on April 22, 1963. Amended Pet. at 1. Prior to the Hep B vaccinations, petitioner’s medical records indicate a complex medical history. In fact, both experts and the filed literature show his medical history at least predisposed him to FM. See, e.g., P Exs 33; P Ex 38 at 1; R Ex A at 10; February 2008 Hearing Trans. at 82:7 (“[I]t is a very complicated history”). This complexity is evident in the record but a brief overview of petitioner’s history illustrates chronic ear infections and sinusitis, perineal pain, allergies, kidney stones, muscle spasms,<sup>4</sup> and back problems associated with disc herniation; the back problems appeared to improve after disc surgery in 1997.<sup>5</sup> Following surgery and the apparent improvement, petitioner still had discomfort in his lower back, his right buttock area and down his right leg. P Ex 3 at 3; P Ex 4 at 27, 30; February 2008 Hearing Trans. 12:5-21; December 2008 Hearing Trans. 36:2-38:7. In November of 1997, petitioner suffered with a different pain in his low back, the cause of which was apparently later diagnosed as kidney

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<sup>4</sup> The preceding medical issues are documented in petitioner’s Ex 6 at 14-22; P Ex 4 at 8-10; P Ex 25 at 9-10; P Ex 52; December 2008 Hearing Trans 6:24-8:7, 17:4-13.

<sup>5</sup> Petitioner’s back problems are documented in petitioner’s Ex 1 at 103-04; P Ex 4 at 39-40; P Ex 6 at 15-17; P Ex 7 at 61, 64, 68, 73, 75, 77-78, 81-82, 188-91, 193, 212-13, 219-20, 224-26; P Ex 8 at 18, 65-66; P Ex 24 at 4; P Ex 26 at 39-40. This problem appears to have improved following surgery. P Ex 4 at 26-29, 30, 35-38; P Ex 7 at 163-64, 168, 176-77; P Ex 26 at 27-29, 30, 35-38.

stones. P Ex 6 at 14-15. Also prior to his first Hep B vaccine, petitioner complained of back pain, soreness and muscle spasms in February 1998. P Ex 6 at 14; P Ex 8 at 73; December 2008 Hearing Trans. 36:2-38:7.

Petitioner also suffers from a history of psychological difficulties, including depression, anxiety and sleep disturbances.<sup>6</sup> Furthermore, his mother and an aunt apparently had FM, which petitioner's expert supposed predisposed petitioner to developing this type of injury. P Ex 33 at 1; see also December 2008 Hearing Trans. 77:25-78:6.

Petitioner received his first Hep B vaccine on March 10, 1998. P Ex 6 at 13. There is no note of a reaction and no visit prior to his second vaccination. Petitioner claims to have developed an ongoing bout of diarrhea after this first vaccination, which "waxed and waned" over the summer of 1998. P Ex 34; December 2008 Hearing Trans. 17:4-18:2, 38:12-39:20, 45:1-48:9. The second Hep B vaccine was given on April 8, 1998, again with no reaction reported during the visit. P Ex 6 at 13. On April 24, 1998, petitioner was evaluated for complaints of right arm and shoulder pain that existed for "2-3 w[ee]ks" and left arm and shoulder pain that began "yesterday." P Ex 6 at 12. Literally read, this record documents a range of onset of shoulder and right arm pain dating from April 3 to April 10; otherwise stated, onset ranges from before the vaccination to shortly thereafter. He was advised to take ibuprofen and return in a week if the pain continued. P Ex 6 at 12; see also December 2008 Hearing Trans. 18:6-16. There is no indication that petitioner returned for a follow-up a week later, though petitioner did visit the same facility on June 26, 1998, for head and chest congestion. Id. at 12. There is no mention of joint or muscle pain in the record of this June 26, 1998, visit. Id. Petitioner then sought help from Dr. Moses in June and August of 1998. P Ex 52 at 6; December Hearing Trans. 21:13-22:10. Petitioner alleged the pain in his upper body continued up until the time of his third Hep B vaccine, but this is only evidenced by his testimony. December 2008 Hearing Trans. 23:2-6. Petitioner reported "LS pain" during the June 12, 1998, visit.<sup>7</sup> P Ex 52 at 7. The August 22, 1998, visit notes "pain in neck." Id.

On September 22, 1998, petitioner received his third Hep B vaccine. P Ex 6 at 11. According to petitioner, he developed a severe headache within twenty-four hours of receiving the third vaccine. December 2008 Hearing Trans. 23:7-14. Shortly thereafter, petitioner testified that he developed upper body pains as well. December 2008 Hearing Trans. 59:2-60:12. At the December 12, 2008, Hearing, petitioner pointed to a September 24, 1998, visit he had with Dr. Moses where he made generalized complaints, documented as what petitioner's counsel referred to as "semantic" complaints. December 2008 Hearing Trans. 23:21-24:19, Dec. 12, 2008. Review of the record shows the wording in this record appears to be "somatic" complaints. Although petitioner's counsel stated he would file evidence regarding the medical meaning of this word,

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<sup>6</sup> These visits are evidenced in petitioner's Ex 1 at 93-99; P Ex 3 at 1-8, 12, 15-17, 18-26; P Ex 5 at 2-13; P Ex 6 at 19-20; P Ex 7 at 38-39, 44-46; P Ex 9 at 4; P Ex 11 at 30; P Ex 52 at 3-4. Again, this is a brief review of petitioner's psychological history, which is detailed in his records.

<sup>7</sup> There are several possible meanings to "LS," including "left-sided," "left shoulder," "lumbosacral."

December Hearing Trans. 24:4-11, nothing was filed.<sup>8</sup> Despite testifying that he had to stay in bed for several hours due to this headache, December 2008 Hearing Trans. 23:10-14, there is no mention of a severe headache post-vaccination in either the Student Health records, P Ex 6 at 11, or in the record of the visit to Dr. Moses, which was just two days after this vaccination, P Ex 52 at 7.

In October 1998, petitioner visited Dr. Keifer, the surgeon who operated on petitioner for his prior back problems. At that time he was experiencing burning neck pain and cramping and burning in his right thigh and calf. P Ex 4 at 25. The physician attributed petitioner's symptoms to degenerative disc disease and referred petitioner to physical therapy. Id. At that time, it does not appear that petitioner received diagnostics to confirm this. On February 19, 1999, petitioner was seen at another facility, the doctor at which inferred petitioner had bursitis in his shoulder and referred him to a rheumatologist. P Ex 8 at 73.

In March 1999, petitioner visited Dr. Goldfarb, a rheumatologist, who noted "wide spread chronic pain." P Ex 7 at 119-23. It is here where petitioner gives a history of diarrhea during the preceding summer, a family history of anxiety and FM, problems with his arms and shoulder that resolved, and pain that developed in several joints. Id. He also complained of fatigue, sleep disturbances and reported his history of lower back problems. Id. The notes indicate petitioner had seen a television program about reactions to the Hep B vaccine. Dr. Goldfarb told petitioner he did not believe petitioner's condition was related to the vaccine and that he believed petitioner had FM.<sup>9</sup> Id.

In April and May of 1999, petitioner was hospitalized for a drug overdose. P Ex 1 at 96. On January 26, 2000, petitioner was seen at Tri-County Pain Management Medicine, where he complained of constant pain in his back, legs, shoulders and feet, arthritis, numbness, weakness, nervous problems and irritable bowel. P Ex 5 at 5-13. He was diagnosed with FM, depression, anxiety and pain in his low back, neck and sacroiliac region. Id. Petitioner was also referred to a

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<sup>8</sup> Somatic: Relating to the soma or trunk, the wall of the body cavity, or the body in general. Stedman's Medical Dictionary, 28th Ed., 2006, at 1788. Petitioner's counsel stated, "[W]e'll file an exhibit about what 'semantic complaints' means . . . . But semantic complaints . . . refer to 'gastrointestinal, constipation, heartburn, nausea, vomiting, colitis, headaches, migraines, backaches, neck aches, and skin disorders' . . ." December 2008 Hearing Trans. 24:4-11.

<sup>9</sup> Petitioner's diagnosis of FM is not in dispute. See, e.g., February 2008 Hearing Trans. at 75:6-7 (Bellanti, February 21, 2008); February 2008 Hearing Trans. at 141:12-14 (Brenner, February 21, 2008); P Ex 33. As testified to by both experts and evident from the literature filed in this case, the causes of FM are not well-understood. See, e.g., February 2008 Hearing Trans. 108:4-11; R Ex I at 1, Adler & Geenen, Hypothalamic-Pituitary-Adrenal and Autonomic Nervous System Functioning in Fibromyalgia, 31 *Rheum. Dis. Clin. N. Am.* 187 (2005); R Ex K at 1, 4-5, Mease, Fibromyalgia Syndrome: Review of Clinical Presentation, Pathogenesis, Outcome Measures, and Treatment, 32 *Journal of Rheum.* 75 (2005). Numerous conditions and events are identified as either possible causes of the condition or associated with it. See, e.g., February 2008 Hearing Trans. 133:11-138:2. A specific biologic mechanism of causation often cannot be pinpointed in cases of FM, nor is it required to prove causation in a Vaccine Act case. See, e.g., Capizzano v. Sec'y of Dept. of Health & Human Servs., 440 F.3d 1317 (Fed. Cir. 2006).

psychiatrist. P Ex 5 at 2-3. The psychiatrist diagnosed petitioner with a generalized anxiety disorder and suggested a treatment plan with life changes rather than the use medication. Id.

Petitioner again visited Dr. Goldfarb on March 27, 2000. P Ex 8 at 34-35. At this visit, petitioner was referred to a neurologist, who saw petitioner on April 10, 2000, and recommended testing. P Ex 8 at 67-68. Radiographs of his thoracic area showed osteophyte formation. P Ex 8 at 60-61. Petitioner thereafter followed up again with Dr. Goldfarb. At this visit, they discussed vaccine reactions and Dr. Goldfarb suggested an EMG and a nerve conduction study. P Ex 8 at 36-37. This visit was followed by an MRI of petitioner's spine in May of 2000, which showed disc herniation, bulge and disc dehydration. P Ex 27 at 162-64.

Multiple visits to physicians and specialists from July 2000 until December 2000 confirm petitioner's diagnosis of FM. P Ex 4 at 19-23, 74; P Ex 4 at 5; P Ex 8 at 42-50; P Ex 15 at 6. In January 2001, a representative of GlaxoSmithKline contacted a physician at the Student Health Center where petitioner was treated while he was in college. Petitioner had contacted the company to report his medical history following his receipt of the Hep B vaccines. P Ex 6 at 6. The director of the Student Health facility completed a Spontaneous Adverse Event Report. Id. at 2-4. Thereafter, visits to physicians in 2004 and 2005 resulted in diagnoses of FM and other maladies. P Ex 9 at 2-5; P Ex 27 at 21-22.

Petitioner filed affidavits containing discussion of his health prior to receiving the vaccinations. P Ex 34. Following petitioner's back surgery in 1997, petitioner says he was "feeling great and extremely active . . . completely functional with the exception of lifting heavy weights." Id. at ¶ 4. Petitioner states that diarrhea, which continued for approximately two years, started within twelve hours of his first Hep B vaccine. Id. at ¶¶ 4-5. At the same time, petitioner states he also experienced pain in both upper arms, his upper back and neck that lasted "for a couple weeks." Id. After his second Hep B vaccine, he states he developed severe pain in his arms, upper back and neck within twenty-four hours. Id. at ¶ 6. And following the third dose, petitioner alleges the pain worsened and included "extreme cranial pressure, headaches, overwhelming anxiety, fatigue, and [the] pain and diarrhea were worse." Id. at ¶ 10. Petitioner's affidavit, medical records and testimony confirm that he suffers from pain and fatigue to the present day. Id.; December 2008 Hearing Trans. 33:8-21.

## II. PROCEDURAL HISTORY

Although originally filed on March 8, 2001, this case languished until 2005. Much of this time appears to have consisted of completing the record. Specifically, the parties had difficulty obtaining records from the Social Security Administration. See, e.g., Order, filed June 29, 2006; Joint Status Report, filed August 1, 2006.

Petitioner filed his first of two expert reports from Dr. Joseph Bellanti on December 14, 2005. P Ex 33, Expert Report of Dr. Bellanti, dated December 12, 2005. Although the report were filed at different times in this case, the reports from Dr. Bellanti are nearly identical. Both reports

review petitioner's medical records<sup>10</sup> and present Dr. Bellanti's opinion that the first symptoms of petitioner's FM followed shortly after petitioner's second Hep B vaccine, which was given on April 8, 1998. P Ex 33 at 1; P Ex 53 at 1-2.<sup>11</sup>

In the first report, petitioner's expert notes the pain in the right arm and shoulder, which migrated to the left arm and shoulder, after the second Hep B vaccine. The report then discusses symptoms following petitioner's third Hep B vaccine; specifically noted are petitioner's report of muscle twinges and cramping, burning sensations in his back and right calf, and neck pain extending into the intrascapular region. Dr. Bellanti opines the back problems may have been related to petitioner's disc surgery but that the neck and shoulder pain "sounds more like FM related to his third" vaccine. P Ex 33 at 1. At this point, and without explanation on how he differentiates these pains, Dr. Bellanti states this is a case of challenge-rechallenge. *Id.* In his testimony, Dr. Bellanti explains his use of the term challenge-rechallenge, which will be discussed later in this opinion. Several of the next pages in his report relay information found in petitioner's medical records and accompanying affidavits. Dr. Bellanti states this is a classic case of FM and lists petitioner's pre-existing conditions as complicating factors. P Ex 33 at 8. He also notes a possible reaction to the first Hep B vaccine based upon petitioner's affidavit. *Id.*<sup>12</sup> He concludes by stating:

It is my opinion that there is a logical sequence of cause and effect by which vaccinations can trigger fibromyalgia in susceptible individuals. This is supported by a reasonable medical theory of causation, and the timing in this case strongly suggests that this is a case of positive rechallenge. My opinion is based on the temporal association with the vaccinations as well as the fact that the symptoms described by [petitioner] well fit those that are described in the medical literature as being associated with the Hepatitis B vaccination.<sup>13</sup> Additionally, the medical work-

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<sup>10</sup> As noted in his report and during the February 2008 Hearing, Dr. Bellanti relied on petitioner's affidavits, which relayed some quantity of information that was not supported by petitioner's contemporaneous medical records. February 2008 Hearing Trans. 90:4-91:1. The discrepancies between petitioner's testimony and the contemporaneous medical records were dealt with in the Order, filed December 16, 2008; see also R Status Report, filed August 1, 2008. The undersigned ruled that the medical records were to be relied upon in this case; this resulted in the direction to discover whether supplemental reports were appropriate from the experts. Dr. Bellanti's second report was a consequence of this finding, as well as of the late-filed medical records.

<sup>11</sup> It should be noted that Dr. Bellanti only pays passing attention to petitioner's medical history of pain and muscle problems prior to the Hep B vaccines; his only reference being to the low back pain associated with petitioner's disc herniation and subsequent surgery. P Ex 33 at 1; P Ex 53 at 1.

<sup>12</sup> During his testimony at the first Hearing, Dr. Bellanti distances himself from this opinion, stating it is more speculative than real, Hearing Trans. 92:4-7, and also acknowledges the petitioner never received a medical work-up regarding the diarrhea to rule out other possible causes. February 2008 Hearing Trans. 121:23-122:9.

<sup>13</sup> In his testimony at the February 2008 Hearing, Dr. Bellanti admitted there was no medical literature linking FM with the Hep B vaccine. February 2008 Hearing Trans. at 107:13-109:19.

up has failed to find an alternative cause for his current condition. While there is a possibility that a number of factors may have come together to result in [petitioner's] development of fibromyalgia, it is my opinion that he would not have developed this condition but for the Hepatitis B vaccines that he received.

P Ex 33 at 8. Dr. Bellanti's second report, P Ex 53, followed the Hearings, the late-filed records and the undersigned's finding that the contemporaneous medical records were to be relied up on for the factual content of this case. Order, filed December 16, 2008. In this second report, Dr. Bellanti offers "the following opinion report where I have tried to rely only on the medical records." P Ex 53 at 1. The first page remains nearly identical to that of the first report, except that Dr. Bellanti qualifies his opinion regarding the timing of petitioner's symptoms after the second vaccine. He points out that the records state onset of the pain in petitioner's right arm started two to three weeks prior to when he sought care. If the symptoms began three weeks prior, they would have predated the vaccine and Dr. Bellanti states he could not offer the same causal opinion. Id. Dr. Bellanti then points out that petitioner consistently gave histories where these first symptoms occurred after the second vaccine. Id. at 2. The remainder of this second report mirrors the first and does not address the records that were newly filed in the case. P Ex 33; P Ex 53. Upon review, the bulk of these reports purports a conclusory opinion that the vaccination caused petitioner's FM. A medical theory, apart from Dr. Bellanti's opinion of a challenge-rechallenge reaction, is not evident.

On September 15, 2006, respondent filed the Rule 4(c) Report, taking the position that petitioner was not entitled to compensation. Respondent's Report, filed September 15, 2006. On September 25, 2006, respondent filed the expert report and *curriculum vitae* from Dr. Alan Brenner. R Ex A, Expert Report of Dr. Brenner; R Ex B, CV of Dr. Brenner. Dr. Brenner's report follows a thorough review of petitioner's medical history, R Ex A at 1-9, and a review of petitioner's affidavits and Dr. Bellanti's report. Id. at 9. In his report, Dr. Brenner does note discrepancies and the lapse in time between the events described and the time the affidavits were prepared for this case. Id. Dr. Brenner starts his own analysis by stating that FM is not a condition mediated by immune inflammatory processes. Id. at 10. He discusses the body's response to vaccines, in particular the cytokine response to the Hep B vaccine. Dr. Brenner presents the cytokine profile in patients with FM, finding cytokine activity is the opposite of that seen in response to the Hep B vaccine. Id. at 9. Dr. Brenner cites literature, appended in a bibliography, in support of his reasoning.

Ultimately, respondent's expert concludes there is no evidence that FM is an immune-mediated condition that could be potentially caused by the Hep B vaccine. Therefore, petitioner could not have suffered from symptoms following the challenge-rechallenge model, which Dr. Brenner strictly uses as a immunologic medical term. Id. at 10. Dr. Brenner continues by focusing on what is known or accepted about FM. He states that most authors agree it is "not related to inflammatory, degenerative or metabolic aberrations in the musculoskeletal tissues where pain is felt." Id. He confirms what is later discussed by Dr. Bellanti in testimony and submitted as medical literature evidence, that the condition is considered to be mediated by the central nervous system. Id. at 10. Dr. Brenner found no literature connecting the Hep B vaccine with FM and concludes that, in his opinion, there is no connection between the Hep B vaccinations petitioner received and his development of FM. Id. at 12.

Approximately one year after filing Dr. Bellanti's first expert report, petitioner filed six articles of medical literature on December 6, 2006. Docket Entry 50, Petitioner's filing Ex 38-44, filed December 6, 2006. These exhibits are labeled by petitioner as "Bellanti References," however, no citations were given in either of petitioner's expert reports, nor was an explanation of the articles' relevance to petitioner's own case found in Dr. Bellanti's direct testimony; the special master presiding over the first hearing questioned Dr. Bellanti of the importance of petitioner's Exhibits 38 through 47. February 2008 Hearing Trans. 117:16-123:13.<sup>14</sup>

Following this, the parties filed medical literature and a chart of contested and uncontested facts. P Exs 38-47; R Exs C-W; Status Report, filed February 13, 2007. On June 22, 2007, both parties filed pre-hearing submissions, which were intended for a hearing originally scheduled in August 2007. Order, filed April 30, 2007. On petitioner's motion, the hearing was rescheduled for February 21, 2008. Order, filed December 11, 2007. The February 21, 2008, Hearing was held before the previous special master assigned to the case, wherein testimony was taken from Drs. Bellanti and Brenner, as well as from petitioner himself. See February 2008 Hearing Trans. Petitioner's Exhibits 49 and 50, filed very shortly before this Hearing, are medical literature and were discussed in Dr. Bellanti's testimony at the hearing. February 2008 Hearing Trans. 70:17-72:14,

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<sup>14</sup> These exhibits were also reviewed by the undersigned. The following is a brief review of Dr. Bellanti's testimony regarding the importance of exhibits 38-47. Exhibit 38, the Albin article, discusses a "model that is based upon observations that suggest that there **may** be a relationship between infection and vaccination, and the onset of fibromyalgia . . ." February 2008 Hearing Trans. 118:7-12 (emphasis added). Exhibit 39, the Bennett article, discusses the psychological stressors associated with FM and presents the broader view of the workings of FM, the tripartite system addressed by Dr. Bellanti. February 2008 Hearing Trans. 118:21-199:20. Exhibit 40, the Cohen/Shoenfeld article, was "only peripherally" relevant to Dr. Bellanti's opinions as it discusses autoimmunity. However, Dr. Bellanti repeats that he is not classifying FM as an autoimmune disease. February 2008 Hearing Trans. 119:21-120:18. And again, Exhibit 41, the Molina/Shoenfeld article, is a piece regarding autoimmune disease, which Dr. Bellanti states can be triggered by vaccines. February 2008 Hearing Trans. 120:19-121:1. Both Exhibits 40 and 41 discuss autoimmune disorders, to which both experts agree FM is not an autoimmune disease. Exhibit 42, the Straud article, discusses the central sensitization theory of FM, which Dr. Bellanti states is not relevant to the issues in dispute. February 2008 Hearing Trans. 121:10-14. Exhibit 43, the second Straud article, again discusses the role of central sensitization. Dr. Bellanti states it is relevant in explaining why petitioner experienced pain in a location different from where he received the vaccine injections, again the central sensitization theory not in dispute. February 2008 Hearing Trans. 121:15-22. Exhibit 44, the Wallace article, Dr. Bellanti presents to link petitioner's diarrhea following his first Hep B vaccine with the onset of a gastrointestinal disorder commonly associated with FM. However, when pressed, Dr. Bellanti states petitioner was not evaluated for the gastrointestinal disorder. February 2008 Hearing Trans. 121:23-122:9. Also, as noted in this decision, Dr. Bellanti said it would only be speculative to call this episode of diarrhea, experienced by petitioner after the first vaccine, the initial challenge event. Exhibit 45, the second Bennett article, discusses diagnosis and treatment of FM. Exhibit 46, the Price article, was referred to as a theoretical article linking pain and the central nervous system, February 2008 Hearing Trans. 122:22-123:4; again, not in dispute. Regarding exhibit 47, the third Straud article, Dr. Bellanti stated its importance was the article describes pain leading to FM, central pain, muscle involvement and management. February 2008 Hearing Trans. 123:5-13.

A number of records not previously filed were discovered and filed with the court after this first Hearing. See Scheduling Order, filed March 7, 2008; P Ex 51, filed March 7, 2008; P Ex 52, filed March 7, 2008; R Ex X, filed May 22, 2008. After reviewing these records, respondent filed the status report on August 1, 2008. The report outlined discrepancies between petitioner's contemporaneous medical records and petitioner's testimony. During this time period, the prior special master assigned to this case left the court. On August 1, 2008, the case was transferred to the undersigned and a status conference was held on August 29, 2008, to discuss the ramifications of this transfer. Order, filed August 1, 2008; Minute Entry, August 29, 2008.

Petitioner subsequently filed a status report on October 14, 2008, requesting a supplemental fact hearing in light of the case transfer and the credibility issues posited in respondent's August 1, 2008, Status Report. P Status Report, filed October 14, 2008. Pre-hearing submissions were filed by the parties on December 2, 2008, and the supplemental Fact Hearing occurred before the undersigned on December 12, 2008. Testimony was taken only from petitioner. See December 12, 2008 Hearing Transcript. Following this Hearing, and as memorialized by the undersigned's Order filed December 16, 2008, the parties were informed that the medical records were to be relied upon for the factual material in this case. "While petitioner's testimony was in many ways consistent with the medical records in a global sense, the detailed nuances of petitioner's complex medical history were in several key areas presented differently between the records and testimony." Id. Particularly, the undersigned found that "petitioner's memory ten years ago of the time line of his symptoms is vastly more reliable than his memory of those events today." Id. at 2.

This Order also directed the parties to contact the experts to ask whether a supplemental report was appropriate given the newly filed records and reliance solely on the contemporaneous medical records. Order, December 16, 2008. Petitioner's expert, Dr. Bellanti, produced the supplemental report, which was discussed previously. P Ex 53, filed June 18, 2009. Respondent declined to file a supplemental expert report from Dr. Brenner as the newly filed records would not alter his opinion. R Status Report, February 3, 2009. As pointed out by respondent in a status report,

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<sup>15</sup> Regarding Exhibit 49, which was filed shortly before the first hearing, petitioner stated it was presented primarily to show that the area of FM is one of interest to Dr. Bellanti, one about which he has written. February 2008 Hearing Trans. 70:17-72:14. This article, Exhibit 49, is also referred to by Dr. Bellanti in his testimony regarding FM and the tripartite network, the neuroendocrine-immunologic systems, many times referred to by him. February 2008 Hearing Trans. 75:8-79:6. Exhibit 50, the Clauw article, was discussed by Dr. Bellanti at the Hearing to describe the general, newer understanding of FM. February 2008 Hearing Trans. 72:21-74:22, 99:25-100:14, 124:3-125:2. When the previous special master questioned Dr. Bellanti about the Clauw article specifically, Dr. Bellanti stated he offered the article because it discusses some of the mechanisms involved and that the condition is viewed by some, including the article's author, to encompass a "continuum of pain and somatic syndromes." Hearing Trans. 124:5-125:2. The general use and content of this article were not disputed by respondent's expert, who expressed a positive opinion of the article. February 2008 Hearing Trans. 131:4-9. This article is discussed later in this decision as it appears that Dr. Bellanti possibly bases a vague theory of causation upon it.

filed on June 19, 2009, Dr. Bellanti's supplemental report was nearly identical to his previously filed report and it did not appear to address the newly filed records; thus, respondent declined filing a reply to Dr. Bellanti's supplemental report. R Status Report, filed June 19, 2009. On August 20, 2009, a telephone conference was held with the parties. Minute Entry, entered August 20, 2009. During this conference, petitioner took the position that no further briefing was necessary in this matter.

### III. LEGAL STANDARD

In Vaccine Act cases,<sup>16</sup> causation can be established either through the statutorily prescribed presumption of causation or by proving causation-in-fact. A petitioner must prove one or the other in order to recover under the Act and, according to 42 U.S.C. § 300aa-13(a)(1)(A), petitioner must prove his case by a preponderance of the evidence.<sup>17</sup>

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions, which create a rebuttable presumption that the vaccine caused the injury or condition if they are found to occur within a prescribed time period. 42 U.S.C. §300aa-14(a). As previously stated, FM is not found on the vaccine table and petitioner is not alleging a "Table Injury." Thus, petitioner must prove that the vaccination in-fact caused his injury, a so-called "off-Table" case.

To demonstrate entitlement to compensation in an off-Table case, the petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused or significantly aggravated the injury alleged. See, e.g., Bunting v. Sec'y of Dept. of Health & Human Servs., 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Sec'y of Dept. of Health & Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Sec'y of Dept. of Health & Human Servs., 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992). See also §§11(c)(1)(C)(ii)(I) and (II). To meet this preponderance of the evidence standard, "[petitioner must] show a medical theory causally connecting the vaccination and the injury." Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Sec'y of Dept. of Health & Human Servs., 165 F.3d 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148;

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<sup>16</sup> As this is an off-Table case, the *prima facie* case consists of the petitioner proving, by a preponderance of the evidence, that (1) petitioner received a vaccine found on the Vaccine Injury Table, (2) her received the vaccine in the United States, (3) he sustained or significantly aggravated an illness, disease, disability, or condition caused by the vaccine, and (4) the condition persisted for more than six months. 42 U.S.C. 300aa-13(a)(1)(A), (c)(1). Elements one, two and four of this list are not in dispute in this case. As described in the text above, Althen v. Sec'y of Dept. Of Health & Human Servs., 418 F.3d 1274,1278 (Fed. Cir. 2005), speaks to the third element, which is at issue in this case.

<sup>17</sup> A preponderance of the evidence standard requires a trier of fact to "believe that the existence of a fact is more probable than its nonexistence before the [special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 372-73 (1970) (Harlan, J. concurring) (quoting F. James, CIVIL PROCEDURE, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

Jay v. Sec’y of Dept. of Health & Human Servs., 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges v. Sec’y of Dept. of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); Knudsen v. Sec’y of Dept. of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, the logical sequence of cause and effect must be supported by “[a] reputable medical or scientific explanation” which is “evidence in the form of scientific studies or expert medical testimony.” Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges F.3d at 960;<sup>18</sup> see also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344.

Regarding the expert testimony, which is particularly crucial in the present case, a petitioner

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<sup>18</sup> The general acceptance of a theory within the scientific community can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that “Daubert is useful in providing a framework for evaluating the reliability of scientific evidence.” Terran v. Sec’y of Dept. of Health & Human Servs., 41 Fed. Cl. 330, 336 (1998), aff’d, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). In Daubert, the Supreme Court noted that scientific knowledge “connotes more than subjective belief or unsupported speculation.” Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert’s opinion. Id. In other words, the “testimony must be supported by appropriate validation – i.e., ‘good grounds,’ based on what is known.” Id. Factors relevant to that determination may include, but are not limited to:

Whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it’s been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), on remand from, 509 U.S. 579 (1993); see also Daubert, 509 U.S. at 592-94.

However, the court also cautioned about rejecting novel scientific theories that have not yet been subjected to peer review and/or publication. The court pointed out that the publication “does **not** necessarily correlate with reliability,” because “in some instances well-grounded but innovative theories will not have been published.” Daubert, 509 U.S. at 594. However, the Supreme Court’s only guidance to lower courts in determining the reliability of a novel proposition is that:

. . . submission to the scrutiny of the scientific community is a component of “good science,” in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Id. at 593-94; see Althen, 418 F.3d at 1280 (“The purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.”); see also, Gall v. Sec’y of Dept. of Health & Human Servs., No. 91-1642V, 1999 WL 1179611, at \*8 (Fed. Cl. Spec. Mstr. Oct. 31, 1999).

may utilize to prove his case, the Federal Circuit has stated that “[a]lthough a Vaccine Act claimant is not required to present proof of causation to the level of scientific certainty, the special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” Moberly v. Sec’y of the Dept. of Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010)(citing Terran v. Sec’y of the Dept. of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999)).

While petitioners need not show that the vaccine was the sole or even predominant cause of the injury, petitioners bear the burden of establishing “that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface, 165 F.3d at 1352-53. A petitioner does not satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating “inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation”)); Hodges, 9 F.3d at 960. Finally, a petitioner does not demonstrate actual causation by solely eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

In Althen v. Sec’y of Dept. of Health & Human Servs., 418 F.3d 1274,1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit reiterated that petitioners’ burden is to produce “preponderant evidence” demonstrating: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury.” Id.; see also Andreu ex rel. Andreu v. Sec’y of HHS, 569 F.3d 1367, 2009 WL 1688231 (Fed. Cir. 2009). In Althen, the Federal Circuit stated further that “requiring that the claimant provide proof of medical plausibility, a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes – is merely a recitation of this court’s well established precedent.” Althen, 418 F.3d at 1281. The Federal Circuit concluded that to support petitioners theory of causation, there is no requirement in the Vaccine Act’s preponderant evidence standard that petitioners submit “objective confirmation,” such as medical literature. Id. at 1279. The Federal Circuit explained that requiring medical literature “prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of the injured claimants.” Id. at 1280 (citing Knudsen, 35 F.3d 543, 549 (Fed. Cir. 1994)); see also Capizzano v. Sec’y of Dept. of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) [hereinafter “Capizzano III”]. Moreover, the Federal Circuit stated, “[t]he purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.” Althen, 418 F.3d at 1280.

The Federal Circuit affirmed Althen’s three-part test in Capizzano III and in Pafford v. Sec’y of Dept. of Health & Human Servs., 451 F.3d 1352 (Fed. Cir. 2006). The panel in Pafford, however, explained that the three prongs in Althen “must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” Pafford, 451 F.3d at 1355. Fairly interpreted, the Pafford court held that it is petitioner’s burden to rule out other competing possible causes of the injury in establishing that the vaccine was the “but-for cause of the harm.” Id. at 1355, 1357; see also Althen at 1281. (“[T]he

elimination of other causes [ ] is merely a recitation of this court’s well-established precedent.”); but see Walther v. Sec’y of Dept. of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007) (“[W]e conclude that the Vaccine Act does not require petitioner to bear the burden of eliminating alternative causes when the other evidence on causation is sufficient to establish a *prima facie* case.”).

However, the legal requirement that petitioners support their proposed causation theory with a “sound and reliable medical or scientific explanation” is undisturbed. Knudsen, 35 F. 3d 543, 548 (Fed. Cir. 1994); see also Grant, 956 F.2d at 1148 (“A reputable or scientific explanation must support this logical sequence of cause and effect.”). Thus, when considering the evidence in a case, the special master is to “consider all relevant and reliable evidence, governed by the principles of fundamental fairness to both parties.” Vaccine Rule 8(c); see also Campbell v. Sec’y of Dept. of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006) (Althen’s requirement of a “reputable medical or scientific explanation” “[l]ogically [ ] requires a special master to rely on reliable medical or scientific evidence . . . .”); Manville v. Sec’y of Dept. of Health & Human Servs., 63 Fed. Cl. 482, 491 (2004) (“Daubert adequately serves the gatekeeping function for analysis of the admissibility of evidence; once evidence has passed that test, the trier of fact’s process, simply, is to determine the probativeness of that evidence.”); De Bazan v. Sec’y of Dept. of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2006) rev’d 539 F.3d 1347 (2008) (reversed on other grounds); Andreu ex rel. Andreu v. Sec’y of Dept. of Health & Human Servs., 569 F.3d 1367, 1382 (Fed. Cir. 2009)(citing Knudsen, 35 F. 3d at 549)(“[T]he function of a special master is . . . to determine ‘based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the . . . injury.’”). Petitioner’s case is measured by these standards.

#### IV. DISCUSSION

Upon review of the record as a whole, petitioner is unable to prove his *prima facie* case by a preponderance of the evidence. Despite not requiring a specific mechanism of causation or objective confirmation, a petitioner must present a plausible theory of causation, a logical sequence of cause and effect showing the vaccine caused petitioner’s injury, and an appropriate temporal relationship between the vaccination and the alleged injury. Neither petitioner’s vague and occasionally ephemeral medical theories, nor his expert’s unsubstantiated conclusion of challenge-rechallenge satisfy the Althen prongs. Specifically, petitioner’s case is almost entirely lacking in evidence regarding an appropriate temporal relationship necessary to satisfy the third prong of Althen.

In this decision, the undersigned will first present the issues not in dispute in this case. Second, the undersigned finds both experts’ credentials and testimony are noteworthy and will be briefly discussed. Third, the undersigned will discuss the critical reason for the denial of this Petition: petitioner’s lack of evidence on the appropriate temporal relationship between the vaccine and petitioner’s injury. Finally, because petitioner’s evidence seemingly fails to distinguish between Althen prongs I and II, the undersigned will discuss the evidence relevant to these two prongs.

##### A. Issues Not in Dispute

Petitioner's diagnosis of FM is not in dispute. See, e.g., February 2008 Hearing Trans. at 75:6-7; February 2008 Hearing Trans. at 141:12-14. Furthermore, the definition of FM was not argued in this case.<sup>19</sup> At the Hearing, fibromyalgia (FM) was described as a "diffuse muscular-skeletal pain syndrome," or a "chronic widespread pain." February 2008 Hearing Trans. at 130; February Hearing Trans. at 73. "Besides the syndrome-defining symptom of widespread pain, prominent symptoms of [FM] include disordered patterns of sleep, ongoing fatigue and mild cognitive impairment such as difficulty with memory and concentration." P Ex 38 at 2. Dr. Bellanti admits, "[i]t is a very complicated area, and we know something about it, but we don't know the final answers . . . ." February 2008 Hearing Trans. at 71:8-10. Current understanding suggests persons with FM have an altered or augmented response to pain, which appears to be linked to their central nervous system. See, e.g., P Ex 50 at 4, Clauw, Fibromyalgia: Updates on Mechanisms and Management, 13 Journal of Clinical Rheumatology 102 (April 2007). As testified to by both experts and evident from the literature filed in this case, the causes of FM are not well-understood. See, e.g., February 2008 Hearing Trans. 108:4-11; R Ex I at 1, Adler & Geenen, Hypothalamic-Pituitary-Adrenal and Autonomic Nervous System Functioning in Fibromyalgia, 31 Rheum. Dis. Clin. N. Am. 187 (2005); R Ex K at 1, 4-5, Mease, Fibromyalgia Syndrome: Review of Clinical Presentation, Pathogenesis, Outcome Measures, and Treatment, 32 Journal of Rheum. 75 (2005); P Ex 38, Albin *et al.*, Fibromyalgia, infection and vaccination: Two more parts in the etiological puzzle, J Autoimm (2006)(referred to as the "Schoenfeld" article during the February 2008 Hearing). Numerous conditions and events, many of which are applicable to petitioner, are identified as being associated with it. See, e.g., February 2008 Hearing Trans. 133:11-138:2.<sup>20</sup> A specific biologic mechanism of causation often cannot be pinpointed in most cases of FM, nor is it required to prove causation in a Vaccine Act case. See, e.g., Capizzano v. Sec'y of Dept. of Health & Human Servs., 440 F.3d 1317 (Fed. Cir. 2006).

## B. Evaluation of Expert Opinions

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<sup>19</sup> The undersigned notes a feature of FM may be disputed by the experts but this issue was not pursued, nor is it particularly germane to this decision. The experts appear to disagree on the manner in which FM arises in a patient. This was not addressed directly but is evident from the experts' testimony. Due to his belief that petitioner suffered from a challenge-rechallenge reaction to the vaccinations, one infers that petitioner's expert finds the onset of fibromyalgia may wax and wane. Dr. Bellanti believes petitioner suffered his first challenge event after his second Hep B vaccine, which then resolved, and the second event after the third Hep B vaccine. P Ex 33 at 1, 8; P Ex 53 at 1-2, 7-8. Respondent's expert unequivocally states that, in his experience, FM usually does not cease once it begins. February 2008 Hearing Trans. at 141:15-143:18. This disagreement is relevant to this case inasmuch as respondent's expert's opinion is some measure of rebuttal evidence against Dr. Bellanti's assertion that petitioner suffered a challenge-rechallenge event, as will be discussed.

<sup>20</sup> Even considering FM's unknown pathogenesis, petitioners have successfully shown causation. See Lee v. Sec'y of Dept. of Health & Human Servs., 2006 WL 5617052 (Fed. Cl. Sp. Mstr. April 8, 2005, reissued with redactions on May 6, 2005); Jane Doe/52 v. Sec'y of Dept. of Health & Human Servs., No. 99-610V, Ruling on Entitlement (Fed. Cl. Sp. Mstr. December 15, 2009); Otteweller v. Sec'y of Dept. of Health & Human Servs., No. 99-519, Ruling on Entitlement (Fed. Cl. Sp. Mstr. May 24, 2010).

Petitioner's medical records alone do not contain evidence required to show causation in this case. In fact, two of petitioner's treating physicians dismissed a connection between the vaccine and petitioner's FM. See, e.g., P Ex 4 at 5; P Ex 8 at 21. Therefore, petitioner's expert evidence is critical. "[I]n vaccine cases, like any other case involving an expert witness, 'assessments as to the reliability of expert testimony often turn on credibility determinations, particularly . . . where there is little supporting evidence for the expert's opinion.'" Doyle v. Sec'y of the Dept. of Health & Human Servs., 92 Fed. Cl. 1, 7 (Fed. Cl. 2010)(quoting Moberly v. Sec'y of the Dept. of Health & Human Servs., 592 F.3d 1315, 1325 (Fed. Cir. 2006)). Dr. Bellanti's *curriculum vitae* was included with his first report, P Ex 33 at 12, and Dr. Brenner's is respondent's Exhibit B. As they are part of the record, an in-depth description of the experts' credentials will not be had. It is acknowledged that the credentials and training of both experts are impressive. However, "proof of causation entails more than having a well-qualified expert proclaim that the vaccination caused a disease." Doyle v. Sec'y of the Dept. of Health & Human Servs., 92 Fed. Cl. 1, 8 (Fed. Cl. 2010).

Dr. Bellanti has numerous appointments, honors and has authored or co-authored many articles. P Ex 33 at 23. Also, he is board-certified in allergy and immunology. February 2008 Hearing Trans. 88:8-11. During the Hearing, petitioner's counsel asked if Dr. Bellanti had "occasion to see and treat patients with FM and other related conditions?" February 2008 Hearing Trans. 70:10-12. Dr. Bellanti replied, "[o]ver the years, and particularly over the past ten or fifteen years, we have seen **at least a hundred patients with chronic fatigue syndrome, fibromyalgia, and related entities.**" February 2008 Hearing Trans. 70:10-16 (emphasis added). Dr. Bellanti clarified on cross examination that "we" refers to his team and himself and that he has personally seen these patients. February 2008 Hearing Trans. 89:12-25. Evident from his *curriculum vitae* and testimony, Dr. Bellanti's professional focus lies in the areas of immunology, microbiology and pediatrics. February 2008 Hearing Trans. 67-70; P Ex 33. Petitioner's exhibit 49 is an article on FM, among other disorders, that Dr. Bellanti and his team have published; though he indicated his team has also published on chronic fatigue syndrome, which Dr. Bellanti states is "part of that whole spectrum of chronic fatigue and fibromyalgia." February 2008 Hearing Trans. 88:17-89:11. At the Hearing, he was qualified as an expert in immunology. February 2008 Hearing Trans. 86:7-87:8.

Dr. Brenner, respondent's expert, also holds numerous appointments and has authored or co-authored several articles. R Ex B. Most notably, Dr. Brenner testified to seeing patients with FM on a weekly basis; in total, he estimated the number of FM patients he has seen to be "**way in the high thousands.**" February 2008 Hearing Trans. 128:18-130:1 (emphasis added). He is board certified in internal medicine, with a sub-specialty in rheumatology. February 2008 Hearing Trans. 128:5-11. At the Hearing, Dr. Brenner was qualified as an expert in rheumatology. February 2008 Hearing Trans. 130:2-7.

Upon review of the articles submitted in this matter, the undersigned notes that most of the articles on FM are found in rheumatology journals and several articles refer to this condition as one seen primarily, but not exclusively, by rheumatologists. See, e.g., P Ex 50 at 4, Clauw, Fibromyalgia: Updates on Mechanisms and Management, 13 Journal of Clinical Rheumatology 102 (April 2007). In his testimony, Dr. Bellanti supported this, stating FM is "area that has been primarily seen by rheumatologists . . ." February Hearing Trans. at 72:25-73:8; see also P Ex 49 at 1 (this article by Dr. Bellanti's team states FM and the related diseases are a "group of diseases that the allergist-

immunologist may be called on to manage. . . ”).

Both experts are qualified to offer opinions in this matter; however, as will be discussed, Dr. Bellanti’s unsupported, often fluctuating testimony undercuts the persuasiveness of his opinion. His testimony was punctuated by broad, strong statements, which he later qualifies or withdraws completely, related to the vaccine causing petitioner’s FM.<sup>21</sup> In the end, it is difficult to know what

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<sup>21</sup> The undersigned was continually perplexed by Dr. Bellanti’s testimony and the lack of followup in his supplemental expert report. Review of the Hearing transcript shows many instances where Dr. Bellanti’s opinion shifts without explanation, becomes inconsistent internally or retreats from previous statements. See, e.g., February 2008 Hearing Trans. at 83:17-21 (Dr. Bellanti claims petitioner developed diarrhea, which he states is irritable bowel syndrome, following petitioner’s first Hep B vaccination); Id. at 92:1-7 (Dr. Bellanti states that considering petitioner’s bout of diarrhea the first reaction to the Hep B vaccine is “more speculative than real”); Id. at 121:23-122:9 (Dr. Bellanti discusses petitioner’s Ex 44, which addresses irritable bowel syndrome, relating it to petitioner’s alleged bout of diarrhea after his first Hep B vaccination, but concedes petitioner was never evaluated for this syndrome); Id. at 84:4-10 (Dr. Bellanti discusses petitioner’s right arm pain as the first reaction to the Hep B vaccine, which occurred within a week of receiving the vaccine. Dr. Bellanti relies upon petitioner’s affidavit for this conclusion, which the undersigned found unreliable.); Id. at 92:1-95:8 (When challenged as to the onset of petitioner’s right arm pain possibly beginning prior to vaccination, Dr. Bellanti inexplicably changes his opinion, relying solely on petitioner’s left arm pain without justifying the timing of this event or explaining how this still constitutes diffuse or widespread pain); Id. at 93:13-94:3 (Dr. Bellanti disregards petitioner’s right arm symptoms when challenged on the date of onset by respondent’s counsel, yet does not explain how this fits his picture of a progression of pain without the right arm symptoms); Id. at 100:12-102:2 (Dr. Bellanti relates his opinion regarding how petitioner developed right sided pain after receiving an injection in his left deltoid, referencing the pain as diffuse, which is only shown in the petitioner’s affidavit); Id. at 84:14-24 (Dr. Bellanti disagrees with petitioner’s treating physician regarding the possible diagnosis of cervical degenerative disease, instead attributing petitioner’s neck pain to FM); Id. at 105:24-107:12 (Dr. Bellanti retreats from his criticism of petitioner’s treating physician when respondent’s counsel calls his attention to the affirmative diagnosis of cervical degenerative disease on May 24, 2001, P Ex 4 at 11); Id. at 90:10-21 (Dr. Bellanti states he could give the same expert opinion without relying upon petitioner’s affidavit); Id. at 92:1-95:8 (Dr. Bellanti states his opinion regarding timing is based upon petitioner’s affidavit); Id. at 116:15-117:15 (Dr. Bellanti again states his opinion regarding timing is based upon petitioner’s affidavit); Id. at 97:7-18 (Dr. Bellanti sidesteps the question of whether FM is an immunologic disease, stating rather that it has immunologic features); Id. at 97:19-99:11 (Dr. Bellanti explains classification of FM as a non-immunologic disorder in his article, P Ex 49, stating the portion of the article “was not designed to talk about fibromyalgia”); Id. at 105:4-23 (Dr. Bellanti dismisses petitioner’s chronic back problems as a possible instigating factor in his FM); Id. at 111:9-25 (When questioned whether a physical injury from shoveling could initiate petitioner’s condition, Dr. Bellanti states “I think anything is possible”); Id. at 114:14-116:14 (Dr. Bellanti attempts to distinguish his use of the term challenge-rechallenge, stating FM is not identified as an immunologically mediated disorder but equivocating when asked if he is implicating an immunological response, “It may or may not be.”); Id. at 119:21-120:18 (Dr. Bellanti utilizes the Shoenfeld article to associate petitioner’s FM with his autoimmunity, then states FM is not an autoimmune disease, and concludes by saying “since [the vaccine] impinges on the immune system, and since fibromyalgia in some way involves the immune system . . ., it indirectly supports a relationship between vaccines and the production of disease caused by vaccines.”); Id. at 121:2-22 (Dr. Bellanti

Dr. Bellanti relies upon, what medical theory he is advocating and ultimately what his basis is for stating the vaccine was causative. Respondent's expert was more persuasive due to his experience with FM. Dr. Brenner's opinion and testimony cripple petitioner's case but, even if one ignores respondent's expert evidence, there is a great likelihood petitioner's evidence still would not satisfy his burden. When reviewing the expert reports and testimony from petitioner's expert, the undersigned is at a loss to find evidence of an appropriate temporal association or to comprehend fully any cohesive theory or rationale for causation.

C. Petitioner's Evidence to Satisfy Prong III under Althen

The third prong of Althen is satisfied when petitioner shows there is medically-accepted temporal relationship between the vaccination and the alleged injury. Althen, 418 F.3d at 1278; De Bazan v. Sec'y of Dept. of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). As with the other prongs used to show causation, it is petitioner's burden to present evidence of an appropriate temporal relationship. Pafford v. Sec'y of Dept. of Health & Human Servs., 451 F.3d 1352, 1358 (Fed. Cir. 2006). Most obviously, the undersigned finds petitioner fails to present evidence showing there was an appropriate temporal relationship between petitioner's receipt of the vaccinations and his development of FM. Upon reviewing the case, forming an opinion on this point is nearly impracticable. Because petitioner's evidence of a temporal relationship, and possibly the other two prongs as well, is based upon Dr. Bellanti's claim of challenge-rechallenge, it will be discussed first.

1. Challenge-Rechallenge Generally

The reports from petitioner's expert state that his opinion regarding causation is based upon challenge-rechallenge. P Ex 33; P Ex 53. The undersigned notes there was disagreement during the February 2008 Hearing regarding the proper use of the term challenge-rechallenge, sometimes also referred to as positive rechallenge. Respondent's expert states challenge-rechallenge is strictly a medical, immunologic term, and FM is not an immunologic or immune-mediated condition. February 2008 Hearing Trans. at 142:23-143:7; 150:16-154:20; 162:17-163:3; R Ex A. Although petitioner's expert never directly disagrees that FM is not an immunologic condition, his testimony often confuses this question. See, e.g., February 2008 Hearing Trans. at 97:7-13; 114:4-116:14; February 2008 Hearing Trans. at 95:19-99:11; 118:17-120:18.

Petitioner's expert, Dr. Bellanti, referred to several usages of the term challenge-rechallenge; including medical, immunological, and legal uses. See, e.g., February 2008 Hearing Trans. at 114:4-116:15. Neither party submitted evidence, other than the experts' testimony at the Hearing, regarding a proper definition, use or application of the term challenge-rechallenge; such as, whether it is only a term to describe an immunologic event within the medical community. The undersigned finds a

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discusses an article petitioner submitted, P Ex 42, stating it involves the central sensitization theory of FM and outcomes of patients with cervical spine injuries, which affected petitioner, but states without explanation that it does not apply directly to petitioner). See also P Ex 53 (Dr. Bellanti states he cannot offer the same opinion if the right-sided pain preceded the vaccination and also fails to address his Hearing testimony relying upon the left-sided pain).

determination of which use is correct to be irrelevant to this case and does not make such a finding. The broad application of the term describing of model of response, as preferred by petitioner's expert, is utilized in this decision. Petitioner's argument that challenge-rechallenge occurred is unsound, his evidence of it is inconclusive at best, and the concept is dismissed in and of itself. Nothing in this opinion should be inferred to make a finding on the use of the concept of challenge-rechallenge. The undersigned merely notes the disagreement in the experts' opinions on the use of the term challenge-rechallenge.<sup>22</sup>

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<sup>22</sup> In Nussman v. Sec'y of Dept. of Health & Human Servs., 83 Fed. Cl. 111 (Fed. Cl. 2008), the judge stated, "[t]he special master explained that '[c]hallenge-rechallenge happens when a person (1) is exposed to one antigen, (2) reacts to that antigen in a particular way, (3) is given the same antigen again, and (4) reacts to that antigen similarly.'" Nussman, 83 Fed. Cl. 111 (citing Nussman v. Sec'y of Dept. of Health & Human Servs., 2008 WL 449656, at \*9 (Fed. Cl. Sp. Mstr. 2008)). Petitioner, at one point during cross examination, states agreement with the definition of challenge-rechallenged identified in Nussman. February Hearing Trans. at 91:15-25 (respondent's counsel asks, "my understanding of rechallenge events is that an individual had an adverse reaction, and then suffers worsening symptoms after a second or third injection." And Dr. Bellanti replies, "That is correct."); but see February Hearing Trans. at 95:19-23 (respondent's counsel asks more specifically, "Rechallenge is an immunological event is it not?" And Dr. Bellanti replies, "It depends on who is using the term. When I use it, yes, it is an immunologic. It is a secondary, booster response.").

In Nussman v. Sec'y of Dept. of Health & Human Servs., 83 Fed. Cl. 111 (Fed. Cl. 2008), the special master pointed out that challenge-rechallenge is not a **theory** of causation per se:

The challenge-rechallenge model is not a medical theory. The challenge-rechallenge paradigm is a method, based in logic, that can assist in proving that a vaccine caused an injury. As such, challenge-rechallenge is discussed in the second prong of Althen. The underlying logic can be used in a variety of disciplines, not just medicine.

Nussman v. Sec'y of Dept. of Health & Human Servs., 2008 WL 449656, \*12 n. 6 (Fed. Cl. Sp. Mstr. 2008), aff'd, 83 Fed. Cl. 111 (Fed. Cl. 2008).

As a theory of causation, challenge-rechallenge was utilized to satisfy the first Althen prong in Capizzano v. Sec'y of Dept. of Health & Human Servs., 2004 WL 1399178 (Fed. Cl. Sp. Mstr. 2004), rev'd on other grounds, 440 F.3d 1317 (Fed. Cir. 2006)(the Federal Circuit did not question the Chief Special Master's finding that the Hep B vaccine could cause rheumatoid arthritis). See also, Capizzano v. Sec'y of Dept. of Health & Human Servs., 2006 WL 3419789, \*12 (Fed. Cl. Sp. Mstr. 2006). This finding was made due to petitioner's submission of multiple published case reports. These reports evidenced challenge-rechallenge events, resulting in arthritic disease, following the receipt of Hep B vaccine in persons other than the Capizzano petitioner. Capizzano v. Sec'y of Dept. of Health & Human Servs., 2004 WL 1399178, \*2 (Fed. Cl. Sp. Mstr. 2004). Further, "[t]he Institute of Medicine (IOM) has stated that rechallenge is proof of causation. . . . The IOM has also stated that where causation is proven, biologic plausibility is a given. Capizzano v. Sec'y of Dept. of Health & Human Servs., 2004 WL 1399178, \*2 (Fed. Cl. Sp. Mstr. 2004)(citing Christopher P. Howson et al., Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines, 48, 53 (1991); Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, 21

Dr. Bellanti expressed agreement with a proposed a meaning of challenge-rechallenge from respondent's counsel, who stated, "my understanding of rechallenge events is that an individual had an adverse reaction, and then suffers a worsening of symptoms after a second or third injection." February 2008 Hearing Trans. at 91:15-19. During testimony, Dr. Bellanti also discussed a truncated latent period, id. at 114:24-115:1, and "heightened response to a vaccine on a second encounter" during questioning on his use of the term, id. at 115:1-19; these truncated latent period was never discussed regarding petitioner's medical history and the heightened response was only discussed as a conclusory statement by petitioner's expert. The undersigned does note that Dr. Bellanti never defined limits to the time frame in which the reactions would or should occur. The undersigned's use herein of the term challenge-rechallenge is consistent with Dr. Bellanti's testimony: a petitioner encounters an environmental agent, here a vaccine, and suffers a reaction thereafter; upon re-administration of the same agent, the petitioner suffers a worsening of the reaction.

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(1994)). It was not disputed that the petitioner in Capizzano did **not** suffer a challenge-rechallenge event. Capizzano v. Sec'y of Dept. of Health & Human Servs., 2006 WL 3419789, \*12 (Fed. Cl. Sp. Mstr. 2006). The published case reports were accepted as evidence of a yet-to-be-identified causal mechanism at work; thus a plausible medical theory was proven by the Capizzano petitioner even though it was not specifically identified. In the case of Capizzano, it was logical that **multiple data points**, the case reports, showing challenge-rechallenge events in published reports logically signal a pattern, one that shows the Hep B vaccine could cause rheumatoid arthritis.

Challenge-rechallenge was used in a slightly different way in Nussman v. Sec'y of Dept. of Health & Human Servs., 83 Fed. Cl. 111 (Fed. Cl. 2008). The special master in Nussman found the petitioner satisfied prong one of Althen through the expert's testimony hypothesizing a delayed hypersensitivity reaction to the vaccine. Nussman v. Sec'y of Dept. of Health & Human Servs., 2008 WL 449656, \*13 (Fed. Cl. Sp. Mstr. 2008), aff'd, 83 Fed. Cl. 111 (Fed. Cl. 2008). Regarding the second prong of Althen, the application of the petitioner's medical theory seemingly depended upon the existence of challenge-rechallenge in the petitioner's actual case. Id. at \*13-15. There, the special master found petitioner's evidence was insufficient to prove the petitioner suffered the challenge-rechallenge event. Id.

Unlike Nussman, and as will be discussed below, petitioner does not offer an intelligible theory of causation necessary for the first prong of Althen. And in contrast to its use in Capizzano, petitioner here does not present evidence that challenge-rechallenge events culminating in FM, evidencing the yet-to-be-identified causal mechanism.

Also unlike the petitioner in Capizzano, none of petitioner's treating doctors attributed his FM to the Hep B vaccine. In fact, two treating physicians addressed and dismissed the vaccines' role in causation. One reference is from Dr. Kennedy. His record states, "Evolution of appropriate hepatitis B antibody - Following vaccination/doubt that the patient's current symptom complex is related to the hepatitis B vaccination." P Ex 4 at 5. He then discusses reactions to the vaccination petitioner received, along with treatment and possible etiology. Id. This narrative includes his impression that "there is an extensive and profound psychiatric component to his current complaints." Id. Dr. Goldfarb also addressed the issue and stated he did not think petitioner's problems were related to the vaccine. P Ex 8 at 21.

## 2. Evidence of Challenge-Rechallenge in Petitioner's Medical Records

There are two problems with Dr. Bellanti's allegation of challenge-rechallenge in this case. First, upon review of the medical records and in light of Dr. Brenner's testimony, the distinct pattern of reaction alleged by Dr. Bellanti's challenge-rechallenge theory is not apparent in petitioner's medical records. Second, and most simply, Dr. Bellanti's opinion of challenge-rechallenge distills into a simplistic temporal association, which is incapable of proving an appropriate temporal association on its own.

First, the most critical problem facing Dr. Bellanti's opinion of challenge-rechallenge is whether a challenge-rechallenge event occurred. This is most evident when considering the initial challenge event may have occurred prior to the second vaccine. This would dissolve or at least disable the expert's belief in a challenge event. Furthermore, considering Dr. Brenner's view regarding the medical records, Dr. Bellanti offered little convincing rationale for identifying a second rechallenge event in petitioner's history after his third vaccination.

To frame this discussion for the reader, Dr. Bellanti testified petitioner developed diarrhea after his first Hep B vaccination, "which is described in the literature with fibromyalgia. This is called the irritable bowel syndrome." February 2008 Hearing Trans. at 83:17-21. Dr. Bellanti later withdrew from this claim, stating it was "more speculative than real" as a reaction to the vaccine, *id.* at 92:1-9, and agreed that petitioner was never evaluated for this disorder. *Id.* 121:24-122:9.

Disregarding the episode of diarrhea, Dr. Bellanti believes petitioner suffered an initial bout of pain following his second Hep B vaccination; this report of pain is found in the medical record from April 24, 1998. P Ex 33 at 1; P Ex 53 at 1; P Ex 6 at 12. "[A]pproximately one month later, [petitioner] received a second Hepatitis B virus vaccine, and within a week of developing or of receiving [this], he developed, first, pain on the right arm, and the right shoulder. Then it became more diffuse in the scapular area, and in the back, and in the cervical area. Then it went to his left shoulder, and his left arm, with inability to raise it beyond 90 degrees." February Hearing Trans. at 84:4-12. The undersigned notes that Dr. Bellanti's description of this pain as diffuse is not supported in the record upon which he relies. *See* P Ex 6 at 12. During his testimony, Dr. Bellanti shifted reliance onto the left arm and shoulder pain as the first challenge event. February 2008 Hearing Trans. at 93. After the Order directing the experts to only consider the history found in the medical records, Dr. Bellanti stated in his supplemental report that he cannot offer this opinion if petitioner's right arm pain preceded the vaccination. P Ex 53 at 1.

Thereafter, Dr. Bellanti believes petitioner suffered a second reaction, the rechallenge event, after petitioner's third Hep B vaccination; this report of pain is found in the record from petitioner's neurosurgeon from October 28, 1998. P Ex 33 at 1; P Ex 53 at 2; P Ex 4 at 25. "Then he received the third vaccine on September 22, and in which now there was an intensification of the pain within two to three days . . . due to fibromyalgia . . ." February 2008 Hearing Trans. at 84:14-16. In his report, Dr. Bellanti states the back discomfort reported on October 28 was likely due to his disc problems, without explanation, and the neck and shoulder pain "sounds like more fibromyalgia

related to his third HBV.” P Ex 33 at 1; P Ex 53 at 2. These two events, the arm and shoulder pains reported in April 1998 and the shoulder and neck pains reported in October 1998, represent challenge-rechallenge to Dr. Bellanti.

Examining the medical records, petitioner’s right arm and shoulder pain started two to three weeks before his April 24, 1998, doctor visit. As stated previously, this places onset of those pains between April 3 and April 10, a span that includes five days before petitioner’s second Hep B vaccination, the day of vaccination, and two days after vaccination. Dr. Bellanti, in testimony, also relied upon petitioner’s complaint of left arm and shoulder pain the day before the medical visit, which would be April 23, fifteen days after vaccination. P Ex 6 at 12. When challenged on the possibility that the right arm pain actually preceded the second Hep B vaccine, Dr. Bellanti inexplicably dropped his reliance on the right-sided pain and relied wholly on the left-sided pain. February 2008 Hearing Trans. 93:10-95:18. Dr. Bellanti provided no reasoning on why one could suddenly dismiss the right arm and shoulder pain when his report and much of his testimony relied upon it. Dr. Bellanti proceeded to discuss “a **progression** of this pain syndrome,” February 2008 Hearing Trans. 93:24-25; however, one fails to see a “progression” of a pain syndrome at this point in the medical records without the pain that began in petitioner’s right arm. The undersigned also observes that the transient arm and shoulder pains do not fit the characterizations of FM given by the experts; both described the FM pain as widespread and diffuse. In his supplemental report, Dr. Bellanti states he could not give the same opinion regarding causation if the challenge event occurred prior to that vaccine. P Ex 53 at 1. However, Dr. Bellanti’s supplemental report did not further address the possibility of the right-sided pain beginning before the vaccine was administered. This supplemental report was submitted after the transcript for the February 2008 Hearing was available, yet Dr. Bellanti does not discuss the reliance on the left-sided pain that he pointed to in testimony if the right arm and shoulder pain preceded the vaccination. Ultimately, Dr. Bellanti’s reference to these pains and his disregard of the right arm pain if it preceded the vaccination leave the undersigned with more questions than answers.

Other than speculation, Dr. Bellanti did not address how he differentiated between the different types of petitioner’s pain. The undersigned finds references to petitioner’s complaints of pain before, in the midst of, and after his series of Hep B vaccinations. Beginning after petitioner’s back surgery, Dr. Keifer notes petitioner said his pain improved since surgery. P Ex 4 at 30; P Ex 26 at 30. On March 17, 1997, a physical therapist noted petitioner stated he had improvement but complained of discomfort about the “L-S” area and a burning sensation in the right buttocks. P Ex 7 at 163-164; P Ex 26 at 27-29. Another visit to Dr. Keifer states petitioner overall felt better but harbored a number of vague complaints April 10, 1997. P Ex 4 at 26. A therapy note on September 16, 1997, appears to note petitioner’s continued pain due to his disc herniation.<sup>23</sup> On February 16, 1998, petitioner reported muscle spasms in his right leg. P Ex 6 at 14. Soreness in his back was also noted, but petitioner or the doctor attributed this to shoveling snow. *Id.* On March 10, 1998, petitioner received his first Hep B vaccination, with no reported reaction found in petitioner’s medical

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<sup>23</sup> Petitioner then presented to Student Health on November 3, 1997, with pain upon awakening; this, however, was eventually explained by petitioner’s kidney stones. P Ex 6 at 14-15.

records. P Ex 6 at 13.

As discussed previously, the second Hep B vaccine was given on April 8, 1998, again with no reaction reported during the visit. P Ex 6 at 13. This was followed by the April 24, 1998, visit where petitioner was evaluated for complaints of right arm and shoulder pain that existed for “2-3 w[ee]ks” and left arm and shoulder pain that began “yesterday.” P Ex 6 at 12. Again, there is no indication that petitioner returned for a follow-up for this complaint, though petitioner did visit the same facility on June 26, 1998, for head and chest congestion. Id. at 12. In fact, after that visit regarding the shoulder pains, petitioner did not return to the clinic, as was advised if the pain continued. When petitioner returned to the Student Health clinic on June 26, 1998, for an upper respiratory infection, the record does not note the issue of shoulder pain. P Ex 6 at 12. Also, a history given by petitioner in the record of Dr. Goldfarb states this shoulder and arm pain resolved. P Ex 7 at 119.

Petitioner then sought help from Dr. Moses in June and August of 1998. P Ex 52 at 6. Petitioner reported “LS pain” during the June 12, 1998, visit. P Ex 52 at 7. The August 22, 1998, visit to Dr. Moses notes “pain in neck.” Id. Petitioner’s third Hep B vaccine was administered on September 22, 1998. It is sometime during this period, the summer of 1998, where Dr. Brenner places onset of petitioner’s FM. February 2008 Hearing Trans. at 141:15-142:18. On October 28, 1998, five weeks after the third Hep B vaccine, petitioner reported a two month history of cramping and burning in his right leg, as well as a one month history of neck and shoulder pain when he visited his neurosurgeon, Dr. Keifer. P Ex 4 at 25.

Testimony given by respondent’s expert, Dr. Brenner, further diminishes petitioner’s dubious expert evidence regarding challenge-rechallenge. Respondent’s expert adamantly denied the existence of challenge-rechallenge in petitioner’s case. February 2008 Hearing Trans. 142:19-143:18, 172:20-25. Admittedly, this was partially due to Dr. Brenner’s use of this term as strictly an immunological term and FM not being accepted as an immune-mediated condition. “Well, in the first place . . . it is not an immunologic event[.]” Id. at 143:9-10. However, Dr. Brenner continued, “in the second place, I don’t see any evidence in the medical record that that is what happened.” Id. at 143:10-12. “In other words . . . [petitioner’s] major manifestations really began according to the medical record in the summer of 1998 . . .” Id. at 141:15-25, 143:13-17. Dr. Brenner’s basis for his own opinion regarding the onset of petitioner’s FM was that he saw petitioner’s pain complex began and **did not abate** after this time. Id. at 141:15-142:18. His convincing reasoning for placing onset at this time was based upon his experience with treating fibromyalgia; that experience being that FM typically does not cease after it begins. Id. at 142:5-12. Dr. Brenner’s opinion was that the transient arm and shoulder pains relied upon by Dr. Bellanti were not the likely onset of petitioner’s FM. Id. at 141:15-142:18; 170:17-172:9. Therefore, Dr. Brenner’s placement of petitioner’s FM onset and his experience with FM not having a transient onset further calls into question whether a challenge-rechallenge event occurred. Dr. Brenner’s review of the medical record is evidence that especially negates a second reaction after the third vaccination. In light of Dr. Brenner’s experience treating thousands of FM patients and his knowledge of the disorder, his assessment is persuasive regarding the course of petitioner’s FM.

The history of pain reported during the October visit coupled with the April 1998 shoulder pain constitutes challenge-rechallenge according to petitioner and his expert. P Status Report at 2, filed February 13, 2007; P Ex 33 at 1; P Ex 53 at 1-2. Beyond making a conclusory note that petitioner suffered from arm, neck and shoulder pain on these occasions, petitioner failed to present any persuasive reason to connect these events or to identify them as challenge-rechallenge reaction. Also, taking into consideration Dr. Brenner's testimony that FM symptoms typically do not abate and his own assessment of the petitioner's onset of FM, Dr. Bellanti's views of challenge-rechallenge are even less persuasive. The undersigned agrees with Dr. Brenner's view that the pain began and did not abate during the summer of 1998, therefore negating the existence of challenge-rechallenge.

The second issue facing petitioner's allegation of challenge-rechallenge is Dr. Bellanti's own testimony regarding the foundation for his claim of challenge-rechallenge. Petitioner's evidence distills into a simplistic temporal association and Dr. Bellanti's unsubstantiated claim of challenge-rechallenge. Dr. Bellanti offered no justification or reasoning for the time between petitioner's second Hep B vaccine and the left or right arm and shoulder pains. He likewise failed to offer evidence justifying the time between his proclaimed rechallenge event and the third Hep B vaccine, which was the history of pain reported on October 28, 1998.

In both of his expert reports, Dr. Bellanti opines petitioner's case is one of challenge, following his second Hep B vaccine, and rechallenge, following his third Hep B vaccine. P Ex 33 at 1; P Ex 53 at 1-2.<sup>24</sup> During his testimony, Dr. Bellanti stated the reason for this belief that petitioner's case was challenge-rechallenge was due to the temporal association between the vaccine and petitioner's symptoms. February 2008 Hearing Trans. 85:6-10, 16; 115:19-24. Ultimately, the temporal relationship is the only basis given for his view regarding challenge-rechallenge, which is insufficient to prove causation in a Vaccine Act case. Beyond a conclusory statement, the expert offers no substantiation for this observation, no discussion of or argument for how the events are connected and no reasoning dealing with the time between vaccination and reaction. Unsubstantiated belief does not amount to a plausible medical theory. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 590 (1993). Without offering more evidence to substantiate Dr. Bellanti's claim of challenge-rechallenge, petitioner's case boils back down to one of a temporal relationship. Just as an unsubstantiated belief cannot support petitioner's case, neither can mere temporal association alone. Grant v. Sec'y of the Dept. of Health & Human Servs., 956 F.2d at 1148.

Respondent's expert did discuss the appropriateness of the time between petitioner's vaccines and Dr. Brenner's placement of onset in the summer of 1998. February 2008 Hearing Trans. 141:15-144:7. Dr. Brenner was asked whether there was significance to the onset of petitioner's FM starting between the second and third Hep B vaccinations. February 2008 Hearing Trans. 143:5-25.

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<sup>24</sup> During his testimony at the February 21, 2008 Hearing, some testimony was given that the diarrhea petitioner claims to have experienced following his first Hep B vaccine was the initial challenge event. However, petitioner's expert himself dismissed this as "more speculative than real," when asked his opinion on what was petitioner's first adverse reaction, the initial challenge event. February 2008 Hearing Trans. 92:1-7.

Respondent's expert explained that this timing was not appropriate "unless it is something with a really long latent period, and that would not be true of a Hepatitis B vaccine." February 2008 Hearing Trans. 143:19-144:7. Although also somewhat conclusory, the explanation from respondent's expert holds slightly more meaning given his experience with FM.

Examining Dr. Bellanti's reports and testimony, it appears that petitioner's expert conclusively relies upon challenge-rechallenge to support the appropriate temporal association prong. The only other reference to the temporal association is by petitioner's expert, who repetitively concluded, "there is an appropriate temporal relationship," without explanation, support or reasoning. P Ex 33 at 8; P Ex 53 at 8; February 2008 Hearing Trans. 85:6-10; 115:19-24. The undersigned finds no persuasive or reliable evidence of what is the appropriate temporal relationship presented by petitioner.

### 3. Petitioner's Evidence Relating to Prong III of Althen is Insufficient

Petitioner's lack of evidence for an appropriate temporal relationship also punctuates his lack of a proposed medical theory in this case. Had petitioner presented a cohesive theory, an opposing party or her expert witness would naturally question whether the timing of events in petitioner's case was appropriate in light of that theory. The above discussion would have addressed more than challenge-rechallenge. Dr. Bellanti's observation of challenge-rechallenge is concluded due to the temporal relationship between petitioner's FM and the receipt of the Hep B vaccines; and the temporal relationship is important, to Dr. Bellanti, because it evidences challenge-rechallenge. P Ex 33 at 1, 8; P Ex 53 at 7-8; February 2008 Hearing Trans. at 89:7-19; 115:19-20. The circular logic of his opinion is evident and does not amount to preponderant evidence on its own. Due to a lack of evidence, the undersigned is simply unable to make any determination regarding whether there was an appropriate temporal relationship between the vaccine and the onset of petitioner's FM. Therefore, petitioner fails to meet his burden regarding Althen prong three.

#### D. Petitioner's Other Evidence

Failure to prove a medically appropriate temporal relationship, in and of itself, ends petitioner's claim. It appears that petitioner's case, **possibly his evidence for all three Althen prongs**, rests upon the existence of challenge-rechallenge in petitioner's medical history. For the same reasons discussed previously, the undersigned cannot accept Dr. Bellanti's opinion of challenge-rechallenge for the first and second prongs of Althen, which test for a plausible medical theory and a logical sequence of cause and effect. However, the undersigned would be loath to overlook other evidence put forth, even if presented in a passing, incomplete or vague manner. Because the undersigned's review of this case is on the record as a whole, it must be acknowledged that petitioner's expert hinted at other arguments.

Specifically during cross-examination, Dr. Bellanti was asked about his opinion of challenge-rechallenge in petitioner's case and responded, "[t]hat is one of the three aspects, yes, of the conclusion." February 2008 Hearing Trans. 91:11-14. The undersigned was unable to find an overt

reference to a three part argument but will address other evidence brought up by petitioner. The manner in which this information was conveyed speaks to its lack of substance.

1. Temporal Association, Symptoms Reported After Hep B vaccine, and Petitioner's Predisposing Conditions

The undersigned finds one possible meaning to the “three aspects” in Dr. Bellanti's reports. The reports discuss the conditions that predisposed petitioner to developing FM and a concluding statement in his second report. P Ex 33 at 8; P Ex 53 at 7-8. Dr. Bellanti states, “[m]y opinion is based on the temporal association with the vaccinations as well as the fact that the symptoms described by [petitioner] well fit those that are described in the medical literature as being associated with Hepatitis B vaccination.” P Ex 33 at 8; P Ex 53 at 8. Throughout both reports, Dr. Bellanti discusses petitioner's conditions that predisposed him to develop FM. This would entail a three-sided theory, if it was intended: 1) the temporal association, which is also referred to as the challenge-rechallenge event Dr. Bellanti sees in petitioner's case; 2) the type of symptoms attributed to the Hep B vaccine in medical literature; and 3) the numerous conditions that predisposed petitioner to acquiring FM, such as genetics, his chronic infections, allergies and his pre-existing psychiatric problems. Beyond the previous discussion that diminishes the timing or challenge-rechallenge events, there are two significant flaws in this reasoning, if this was the “three aspect” rationale to which Dr. Bellanti refers.

Regarding the symptoms reported following the Hep B vaccine in the medical literature, a review of the submitted literature finds that conditions linked to the Hep B vaccine include: central nervous system demyelination, R Ex F, multiple sclerosis, P Ex 41 at 2, arthritis, erythema nodosum, Reiter's syndrome, myasthenia gravis, uveitis, systemic lupus erythematosus, and Evan's syndrome. P Ex 40 at 2 table 1. Notably however, Dr. Bellanti agreed with petitioner's diagnosis of FM and consider's petitioner's a classic case of FM. P Ex 33 at 8; P Ex 53 at 7. The first flaw is that petitioner failed to present any evidence likening petitioner's injury, FM, to any of the conditions associated with the Hep B vaccine in the submitted literature.

A second flaw is that petitioner fails to show evidence that the **symptoms** of FM are caused by similar disease processes that result in the symptoms of those conditions listed above. If Dr. Bellanti was generally referring to petitioner's myalgias and arthralgias, he failed to show how the aches and pains associated with FM are due to the same processes that cause aches and pains in conditions like rheumatoid arthritis. Also, petitioner submitted the Clauw article, P Ex 50, which touches upon the stark differences between diagnosing arthritic conditions and diagnosing FM. He explains that misdiagnosis of an arthritis condition occurs because if you do multiple x-rays, “you will always **find something wrong**.” *Id.* (emphasis added). Dr. Clauw then relates an anecdote about effectively diagnosing FM at a veterans clinic. The radiograph studies of patients diagnosed with osteoarthritis or chronic low back pain were brought to him. If he could find a patient with ten consecutive films **without abnormality**, that was the proper diagnostic test for FM. To be clear, Dr. Clauw's anecdote implies that one finds abnormality on radiographs of arthritic patients, whereas one would not find abnormalities on radiographs of FM patients. Although this anecdote is not relied

upon heavily to undercut Dr. Bellanti's speculative opinion, it is some evidence that the mechanisms causing joint or muscle pain in arthritic patients differ from those causing similar types of pains in patients with FM. Dr. Brenner also testified that "there is a huge difference between arthritis and fibromyalgia . . . apples and oranges." February 2008 Hearing Trans. 138:3-139:4. Again, considering Dr. Brenner's experience with FM and rheumatology, his statement carries ample weight. Petitioner simply did not offer evidence that the symptoms of FM occur because of the same disease processes that cause those symptoms in the conditions that are associated with Hep B vaccine.

Regarding the final possible third leg of this argument, if it was indeed what petitioner or his expert intended, the numerous conditions that predisposed petitioner to have FM do nothing but weaken and distract from petitioner's argument. Petitioner's pre-existing conditions associated with FM include: a genetic predisposition, his history of allergies and infections and his psychological difficulties. P Ex 33 at 1; P Ex 53 at 1; R Ex A at 10-12. Whereas the Hep B vaccine has not been linked to FM, petitioner's other pre-existing conditions have been associated with FM. The association between FM and petitioner's other conditions is acknowledged in literature submitted by both parties and discussed in the experts' reports. Other than Dr. Bellanti's unsubstantiated belief, petitioner has not presented any evidence why the Hep B vaccine, which has yet to be linked to FM, is more likely to be a substantial cause of his injury than petitioner's pre-existing conditions.

To be clear, the undersigned is not requiring medical literature from petitioner. However, the literature submitted by both parties discusses petitioner's other conditions as being accepted to have at least an association with FM. See, e.g., P Ex 40; P Ex 41; R Ex F. Therefore, on one hand, the undersigned sees petitioner's medical expert alone associating FM with the Hep B vaccine. On the other hand, the undersigned sees both medical experts and the submitted medical literature acknowledging an association between FM and petitioner's other pre-existing conditions. See generally Doe 11 v. Sec'y of the Dept. of Health & Human Servs., 601 F.3d 1349, 2010 WL 1441776 (Fed. Cir. 2010)(approving the use of evidence of possible alternative causes as rebuttal evidence). Also, respondent's expert denies any association between Hep B vaccine and FM and there is silence on this issue in the medical literature submitted. Furthermore, as noted previously, petitioner's medical records evidence two treating physicians discounting the possibility that the Hep B vaccinations caused his FM. P Ex 4 at 5; P Ex 8 at 21. Examining the evidence as a whole, petitioner has not offered any evidence or logical argument that the Hep B vaccine was a "but for" cause or a substantial factor causing his FM.

## 2. Neuroendocrine-Immunological Network - the Tripartite System

By examining his testimony numerous times, the undersigned believes Dr. Bellanti may have also been referring to the tripartite system that is involved in FM patients, which is discussed in Dr. Bellanti's article. P Ex 49. This was difficult to find in the expert testimony and may not have been intended at all. Although discussed at length in his testimony, the tripartite system makes no appearance in Dr. Bellanti's reports. Upon reviewing testimony, the undersigned finds references from Dr. Bellanti regarding the neuroendocrine-immunological network described in petitioner's Ex 49, Bellanti, *et al.*, Are Attention Deficit Hyperactivity Disorder and Chronic Fatigue Syndrome

## Allergy Related? What Is Fibromyalgia?.

The article presents a “central unifying hypothesis,” which postulates the neurological, endocrine and immunologic systems “**may** be affected in ADHD, CFS and FM.” P Ex 49 at 9, figure 10 (emphasis added). Nothing about this hypothesis seems illogical, nor did respondent’s expert refute it. However, no effort was made to show that petitioner evidenced a reaction to the Hep B vaccine that affected any of these three bodily systems. Dr. Bellanti himself equivocally states, twice, that petitioner’s response to the vaccine may or may not have been immunologically mediated. February 2008 Hearing Trans. 115:25, 116:6-14. Dr. Brenner’s report states “[i]t is generally accepted that [FM] is **not** a condition mediated by immune inflammatory processes . . .” R Ex A at 10. Dr. Brenner also offered testimony that FM not being an immunologic disorder. See, e.g., February 2008 Hearing Trans. at 143:1-7.

Beyond the immune system, no evidence was presented to show that the Hep B vaccines impacted petitioner’s neurological or endocrine systems. Ultimately, this theory, again if it was even intended, is so overly broad that it is virtually meaningless.

### 3. Dr. Bellanti’s Reliance on the Submitted Medical Literature

First, Dr. Bellanti references petitioner’s Exhibit 38 as evidence of a link between FM and vaccination. February 2008 Hearing Trans. at 80:25-81:3; 107:13-109:19; P Ex 38, Fibromyalgia, infection and vaccination: Two more parts in the etiological puzzle by Albin, Shoenfeld and Buskila. Review of this article shows it hypothesizes a connection between FM and vaccines and infection. Dr. Bellanti uses the article to say vaccines, generally, have been linked to FM and the related disorders. February 2008 Hearing Trans. at 80:25-81:3. When questioned by the Special Master at the Hearing, Dr. Bellanti clarified the scope of the article, stating it suggests a model, possibly implicating a role for vaccines affecting FM. February 2008 Hearing Trans. at 109:5-19; 117:16-118:16. The article’s authors state, “in this review we have attempted to describe the current knowledge on two related factors . . ., i.e. the association of fibromyalgia with either infection or vaccination.” P Ex 38 at 1. Portions of the article relevant to Dr. Bellanti’s testimony discuss or hypothesize possible association between FM and the following: hepatitis C infection, P Ex 38 at 4-5; rubella and Lyme disease vaccinations, id. at 5; and multiple vaccination exposure or multiple vaccination exposure during periods of stress or trauma for the recipient, such as in servicemen in the Gulf War, id. at 5-6. Even in the last example of multiple vaccination exposure, the Hep B vaccine is not identified among the several vaccines listed by the authors as being received by the servicemen. One must also consider the fact that the article merely hypothesizes vaccines and infections could be causative of or associated with FM. Furthermore, the authors state, “it appears that not the mere exposure to one or another particular vaccine but rather the combination between various vaccines, adjuvant, and additional moderating factor such as stress **may** govern the effect of vaccination on the immune system and on the eventual development of chronic unexplained symptoms including fatigue, mood and cognition disturbances and pain.” P Ex 38 at 6.

Dr. Bellanti also references the articles relating to autoimmunity that petitioner has filed in

this matter. February 2008 Hearing Trans. at 119:21-120:7; 120:19-121:1. However, as stated previously, both experts agree for the most part that FM is not an immunologic disorder. February 2008 Hearing Trans. at 142:23-143:7; 150:16-154:20; 162:17-163:3; but see February 2008 Hearing Trans. at 97:7-13; 114:4-116:14; February 2008 Hearing Trans. at 95:19-99:11; 118:17-120:18 (Dr. Bellanti often states FM is not an immunologic condition but then equivocates, postulating a role of petitioner's immune reaction to the vaccine in causing his FM). When pressed regarding petitioner's Exhibit 40, Cohen & Shoenfeld, Review, Vaccine-induced Autoimmunity, Dr. Bellanti states the article is only indirectly relevant to petitioner's case as he is not identifying FM as an autoimmune disease. February 2008 Hearing Trans. at 119:21-120:7.

Other than suggesting FM somehow affects or is affected by the immune system, Dr. Bellanti does nothing to develop a theory relying on these articles, he simply proposes the Hep B vaccine affected one of the three systems identified, causing petitioner to develop FM. Dr. Brenner testified that he was unable to find evidence, literature or studies, that vaccines are a trigger for FM. February 2008 Hearing Trans. at 138:3-17. Without more, which was not provided by petitioner or his expert, these articles fail to advance or flesh out petitioner's case.

#### 4. Petitioner's Evidence on Prongs I and II of Althen Is Insufficient

The record is viewed as a whole when considering whether petitioner has established the *prima facie* case. 42 U.S.C. § 300aa-13(a)(1). Two important elements the undersigned finds persuasive are Dr. Brenner's experience with FM, making him a more qualified expert on FM, and the fact that two of petitioner's treating physicians denied the Hep B vaccinations caused petitioner's FM. Considering Dr. Bellanti's muddled evidence of a plausible theory and a logical sequence of cause and effect, petitioner failed to establish the first two prongs of Althen.

## V. CONCLUSION

It is true that the Vaccine Act does not require petitioner to offer the exact mechanism that caused the injury. See, e.g., Knudsen v. Sec'y of Dept. of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994); Bunting v. Sec'y of Dept. of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). However, as recently stated in Hennessy v. Sec'y of Dept. of Health & Human Servs., 91 Fed. Cl. 126, 134, "[t]he special master may not demand scientific certainty, but neither may she accept mere speculation." Petitioner's evidence regarding a theory of causation and a logical sequence of cause and effect is mere speculation by petitioner's expert, unsubstantiated by evidence or the expert's reasoning. Dr. Bellanti's testimony cannot withstand scrutiny when examined. Petitioner appears to present the concept of challenge-rechallenge to satisfy the third prong of Althen, and possibly all three Althen prongs. Dr. Bellanti's factual interpretation of the medical record was unconvincing and seemed self-serving when viewed with the evidence Dr. Brenner presented on FM and in the medical records. Beyond Dr. Bellanti's somewhat tortured factual interpretation, he provided no rationale for his opinion of challenge-rechallenge beyond a basic temporal association. Petitioner's unsubstantiated and wholesale attempt to satisfy one, if not all, of the requirements of the Act with the concept of challenge-rechallenge was unpersuasive.

A petition must be supported by medical records or expert evidence. Even though petitioner is not required to present specific types of evidence, such as epidemiological studies or medical literature, the special master must inquire into the reliability of an expert's opinion and testimony. Moberly v. Sec'y of Dept. of Health & Human Servs., 592 F.3d 1315, 2010 WL 118661, 1324 (Fed. Cir. 2009). Petitioner's case presents numerous flaws, those being: the ambiguity found in petitioner's medical records regarding onset of petitioner's symptoms, the dismissal of the vaccine as the causative agent by two treating physicians, petitioner's complex medical history of conditions known to be associated with FM, the tenuous evidence offered by petitioner's expert, the failure to prove an appropriate temporal relationship between vaccine and injury, and the lack of a meaningful medical theory or evidence of a logical sequence of cause and effect. Petitioner fails to prove his *prima facie* case. Ultimately, this petitioner's theory and case boil down to an unexplained temporal association and "amount[] to little more than an unsubstantiated possibility, which is far short of the standard required under Althen." Spates v. Sec'y of Dept. of Health & Human Servs., 76 Fed. Cl. 678, 685 (Fed. Cl. 2007); Knudsen v. Sec'y of Dept. of Health & Human Servs., 35 F.3d at 548 (proof of actual causation "must be supported by a sound and reliable medical or scientific explanation.").

The court must deny entitlement to compensation. The Clerk shall enter judgment accordingly.

**IT IS SO ORDERED.**<sup>25</sup>

s/Gary J. Golkiewicz  
Gary J. Golkiewicz  
Special Master

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<sup>25</sup> This document constitutes a final "decision" in this case pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). Unless a motion for review of this decision is filed within 30 days, the Clerk of the Court shall enter judgment in accord with this decision.